

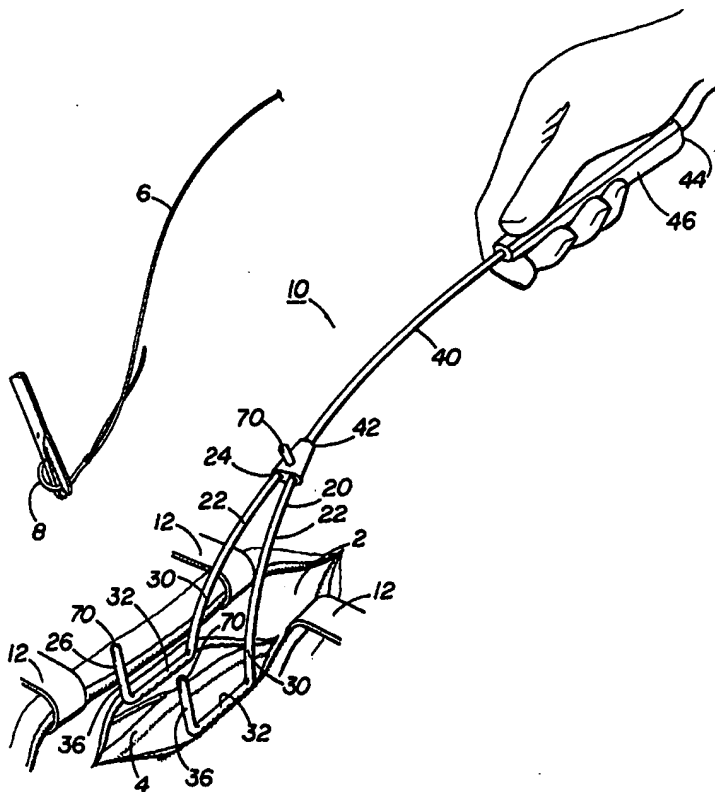
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/02	A1	(11) International Publication Number: WO 98/17182 (43) International Publication Date: 30 April 1998 (30.04.98)
(21) International Application Number: PCT/US97/17411 (22) International Filing Date: 25 September 1997 (25.09.97) (30) Priority Data: 60/026,905 26 September 1996 (26.09.96) US (71) Applicant: GENZYME CORPORATION [US/US]; One Mountain Road, Framingham, MA 01701 (US). (72) Inventors: LOONEY, Christopher, S.; 1418 Calibre Creek Parkway, Roswell, GA 30076 (US). FURNISH, Gregory, R.; 2614 Top Hill Road, Louisville, KY 40206 (US). HIPPS, Michael, W.; 515 Cranberry Place, Roswell, GA 30076 (US). (74) Agents: ALTERA, Allan, G. et al.; Needle & Rosenberg, 127 Peachtree Street, N.E., Atlanta, GA 30303 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: ADJUSTABLE MULTI-PURPOSE CORONARY STABILIZING RETRACTOR**(57) Abstract**

This invention is an apparatus (10) for stabilizing a predetermined area on a heart (2) of a patient to enable a surgical procedure to be performed. The apparatus includes a bifurcated member (20) having two elongated prongs (22) which can be adjustable as to width, and an elongated handle segment (40) attached to the bifurcated member. The handle segment can be either fixed or pivotally attached to the bifurcated member. The apparatus may further include an attachment (14) or inlay to prevent lateral movement thereof when being used in the surgical procedure. The apparatus may also include a cleat (70) for securing a portion of the surgical thread (6) used during the procedure. At least a portion of the prongs (or feet) of the bifurcated member may be further independently rotatable for self-alignment with the surface of the predetermined area of the heart.



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ADJUSTABLE MULTI-PURPOSE CORONARY STABILIZING RETRACTOR

This application is a continuation-in-part of Serial Number 08/639/214, filed on April 26, 1996 and claims priority in Provisional Application Serial Number 60/026,905,
5 filed on September 26, 1997.

BACKGROUND OF THE INVENTION**Field of the Invention**

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This invention relates to an apparatus for stabilizing a predetermined area of the body during surgical intervention, which better enables a surgeon to perform a surgical procedure at the predetermined site. In particular, the invention relates to a hand held or retractor mounted apparatus for stabilizing a predetermined area of the heart for
15 performing minimally invasive coronary artery bypass grafting at the surgical site which has adjustable tool end comprised of substantially at least two parallel prongs (tines or feet) with actuator means to allow for adjustment of the spacing between the tines and wherein the tines are also moveable so as to be self-aligning with the surface of the heart.

20

Background Art

Atherosclerosis or coronary artery disease is among the most common and serious health problems confronting the medical profession. In the past, many different
25 approaches at therapy have been utilized. Surgical correction of occluded or stenosed coronary arteries via bypass grafting through conventional approaches, such as the sternotomy, are probably still the most common procedure performed today, especially where multiple bypass grafts are needed.

30

However, interventional techniques, such as percutaneous transluminal angioplasty (PTCA), have gained popularity as the method of choice for therapy of atherosclerotic occlusions for several reasons. The transluminal approach is a minimally invasive technique which subjects the patient to less trauma and less recovery time,

especially when compared to bypass grafts which utilize homologous tissue, such as saphenous vein grafts. Often the patient suffers complications at the graft donor site which are worse than the sternotomy and anastomosis.

5 Although PTCA procedures are often successful, complications such as restenosis or thrombosis and embolism can occur. Intravascular stents are sometimes deployed at the PTCA site to lessen the occurrence of restenosis. However, restenosed vessels often require surgical intervention for correction.

10 Surgical correction of restenosis, as well as conventional bypass graft surgery, require that the heart be stopped and the patient placed on a heart/lung bypass machine during the procedure. This occurs at considerable expense and risk to the patient. In an effort to reduce the expense, risk and trauma to the patient, physicians have recently turned to minimally invasive surgical approaches to the heart, such as intercostal and
15 endoscopic access to the surgical site. In addition, utilization of alternative graft vessels, such as the internal mammary artery (IMA), have also greatly reduced the trauma to the patient and increased the efficacy of surgical therapy.

 Prior to the present invention, however, attempts at performing minimally
20 invasive bypass grafting on a beating heart were thought to be too tedious, dangerous and difficult because of the delicate nature of the surgical procedure, the lack of adequate access through a reduced surgical field, and the lack of a way to adequately stabilize and reduce movement at the graft site. Such a minimally invasive bypass grafting performed on the beating heart eliminates the expense and risk of stopping the
25 heart and the necessity of the heart lung bypass machine and decreases patient recovery time. For single or double bypass procedures, especially where the IMA is utilized, patient trauma and recovery time is even further decreased.

SUMMARY OF THE INVENTION

The above problems of the prior art are overcome by the present invention which provides an apparatus for stabilizing a predetermined area on a heart or other organ of a patient to enable a surgical procedure to be performed. The apparatus of the present invention comprises a bifurcated member having at least two elongated prongs, an elongated handle segment, and a means for joining the handle member to the bifurcated member. Each prong of the bifurcated member may have a first section, a second section, and a third section. The first section is adjacent the handle segment and terminates in the second section. The second section engages the heart or other organ that the surgical procedure occurs and terminates in the third section.

In one embodiment the bifurcated prongs (tines or feet) may be substantially parallel to one another along at least a portion of their bodies and may further comprise a means for movement of the tines between an open and a closed position to increase or decrease the width or spacing between the parallel portions. The moving means can comprise a scissor hinge assembly attached to an actuator rod which passes through a bore in the handle to means for selective movement of the actuator rod allowing the surgeon to space the tines at a desired distance (width) apart.

Since the second section engages the heart, it is desired that the second section further comprises a means for stabilizing it from sliding on the heart. Stabilizing the apparatus on the heart is an important consideration during the surgical procedure. The present invention can encompass many different stabilizing means, including, for example, a textured portion on at least a portion of one second section, an insert disposed on the second section having a plurality of teeth, an insert having a plurality of flexible hooks, an insert having a plurality of bristles, or even a flexible covering disposed over at least a portion of the second section. The flexible covering can be a cloth, such as cotton, or a tubular member formed from a material such as silicon.

In a further embodiment, the section which engages the heart can be fenestrated using slots or holes interspersed between or among a textured gripping surface. When this section is applied to the surface of the heart, a portion of the heart tissue gently and atraumatically pouches up into or fills the fenestrations or openings to further stabilize the heart and prevent slippage of the stabilizing device at the desired surgical site.

One embodiment of the invention comprises bifurcated prongs wherein a first portion terminates in a means for allowing rotational movement of a second and or third portion in a desired plane that can be generally perpendicular to the longitudinal axis of the first portion. Rotational stops can be placed on the first and second portions to limit the rotational movement to a desired range. The independently rotatable portion, e.g., a prong, tine or foot is self-aligning with the surface of the heart in the deployed position.

Another aspect of the present invention is that it further comprises a means for securing a portion of a surgical thread that can be used in the surgical procedure. In the preferred embodiment, the securing means comprises at least one cleat disposed on the apparatus. The cleat or cleats can be disposed in the end of the third section of each of the prongs and/or disposed on the handle segment or the bifurcated member adjacent the first section or both.

20

In another embodiment of the present invention, the joining means comprises a means for pivotally connecting the handle segment to the bifurcated member. This can be achieved by a socket disposed on the handle segment and a ball joined to the bifurcated member, wherein the ball is sized to be complementarily received within the socket. To facilitate use of the present invention, it preferably further comprises a means for locking the ball in a selective position within the socket so that the handle segment is disposed at a desired pivotal orientation relative to the bifurcated member.

Thus, it is an object of the invention to provide an apparatus for stabilizing a predetermined area of the heart of a patient to enable a surgeon to perform a surgical procedure at the predetermined site.

It is another object of the invention to provide an apparatus which stabilizes a predetermined area of a beating heart to enable a surgeon to perform a surgical procedure at the predetermined site.

- 5 A further object of the invention is to provide an apparatus for stabilizing a predetermined area of the heart which further comprises means for anchoring tension or ligation sutures.

- Yet another object of the invention is to provide an apparatus for stabilization of
10 an area of the beating heart adjacent to a coronary artery for performing coronary artery bypass grafting.

- Another object of the invention is to provide an apparatus as above which is further adapted for pivotal attachment to a device which provides access to the surgical
15 site such as a rib spreader or other retractor.

 Another object of the invention is to provide an apparatus for stabilization of a predetermined area of the body to enable a surgical procedure at the predetermined site.

- 20 A further object of the invention is to provide an apparatus which is capable of stabilizing a predetermined area of the body that can also function as a tissue retractor to assist the surgeon in accessing the surgical site.

- It is another object of the invention to provide an apparatus which has adjustable
25 substantially parallel prongs (tines or feet) which allow the surgeon to preselect the width or distance between the prongs.

- It is yet another object of the invention to provide an apparatus having prongs (tines or feet) which are independently rotatable and self aligning with the surface of the
30 heart when in the deployed position.

It is another object of the invention to provide an apparatus which has fenestrated using slots or holes interspersed between or among a textured gripping surface on the prongs (tines or feet) such that when applied to the surface of the heart, a portion of the heart tissue gently and atraumatically pouches up into or fills the fenestrations or openings to further stabilize the heart and prevent slippage at the predetermined surgical site.

The above recited objects of the invention are not intended to so limit the used of the invention. These and other objects of the invention will be apparent to the skilled artisan based upon the following disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of one embodiment of the present invention showing the apparatus being place on the heart of a patient to perform a surgical procedure.

Fig. 2 is a perspective view of one embodiment the stabilizing means of the present invention comprising a textured portion on the second surface of the prongs of the bifurcated member.

20

Fig. 3 is an alternative embodiment of Fig. 2 in which the stabilizing means comprises an insert having a plurality of teeth.

Fig. 4 is an alternative embodiment of Fig. 2 in which the stabilizing means comprises a plurality of flexible hooks.

25

Fig. 5 is an alternative embodiment of Fig. 2 in which the stabilizing means comprises a plurality of bristles.

Fig. 6 is an alternative embodiment of Fig. 2 in which the stabilizing means comprises a flexible covering disposed over the second surface of the prongs of the bifurcated member.

5 Fig. 7 is an alternative embodiment of Fig. 6 in which the flexible covering is a tubular member.

Fig. 8 is an elevated front view of one embodiment of a cleat for use with the present invention.

10

Fig. 9 is an alternative embodiment of the cleat shown in Fig. 8.

Fig. 10 is an alternative embodiment of the cleat shown in Fig. 8.

15 Fig. 11 is an alternative embodiment of the cleat shown in Fig. 8.

Fig. 12 is another embodiment of the present invention in which the handle is pivotally connected to the bifurcated member.

20 Fig. 13 is a cut away perspective view of one embodiment of the invention showing means for actuation of the bifurcated prongs (tines or feet), including a scissors linkage assembly, actuator rod and prong (or tine) width adjustment knob and boss assembly on the handle.

25 Fig. 14 is a perspective view of the adjustable width prongs (or tines).

Fig. 15 is a perspective (or top plan) view of the embodiment of the invention shown in Fig. 14 with the prongs (or tines) in the open position.

30 Fig. 15A shows the prongs (or tines) in the closed position.

Fig. 16 is a perspective view of one embodiment of the invention showing independently rotatable prongs (tines or feet) and means for actuation of the scissor extension links (or a first section of the prongs).

- 5 Fig. 17 shows an alternate means for linkage of the actuator rod to the scissors linkage assembly shown in Fig 16.

Fig. 18 is an exploded view of the rotational mechanism and stops of the rotating prongs (tines or feet) shown in Fig. 16.

10

Fig. 19 shows an alternate embodiment of the invention wherein rotatable textured sleeves are covering a portion of the prongs (tines or feet) shown in Fig 16.

- Fig. 20 is a perspective view of an alternate embodiment of the stabilizing tines or
15 prongs showing fenestrations or holes through the tines for capturing cardiac tissue to increase stabilization at the predetermined site.

Fig 21 is a bottom plan view of the embodiment shown in Fig 20.

- 20 Fig 22. is an rear elevational view of the embodiment shown in Fig 20.

Fig 23 is side elevational view of the embodiment shown in Fig 20.

- Fig 24 is an enlargement of the inset at circle A of Fig 23 showing the textured surface
25 of the bottom of the tines or prongs.

DETAILED DESCRIPTION OF THE INVENTION

- The present invention is more particularly described in the following examples
30 which are intended as illustrative only since numerous modifications and variations

therein will be apparent to those skilled in the art. As used in the specification and in the claims, "a" can mean one or more, depending upon the context in which it is used.

5 The present invention, as shown in Figs. 1-12, encompasses an apparatus 10 for stabilizing a predetermined area on a heart 2 of a patient to enable a surgical procedure to be performed. The apparatus 10 comprises a bifurcated member 20, an elongated handle segment 40, and a means for joining the handle segment 40 to the bifurcated member 20. It is preferred that the bifurcated member 20 and the handle segment 40 be constructed of stainless steel or other acceptable material for surgical instruments.

10

It can be appreciated by one skilled in the art that the apparatus of the present invention can be utilized at any location on or within the body where tissue stabilization or isolation of a predetermined area is desired, including but not limited to the heart, liver kidneys, bladder, stomach, intestines, and vascular and other soft tissue surgery.

15 As set forth in greater detail below, the unique design of the apparatus also provides the added feature of using the apparatus as a tissue retractor for use, *e.g.*, in gaining access to a predetermined surgical site.

The present invention is ideal for use in heart surgery, in either conventional

20 open heart surgery or by minimally invasive surgery, *e.g.*, minimally invasive coronary artery bypass grafting. For minimally invasive surgery, access to the heart 2 may be achieved through the ribs of the patient using a rib spreader 12, as shown in Fig. 1. In the typical procedure, the surgeons will usually access the heart via the fourth intercostal space located between the third and fourth ribs, but this may be changed based on the

25 individual patient's anatomy. Since, for the above reasons, this procedure is sometimes performed on a beating heart 2, it is advantageous to stabilize the heart 2 in the area that the surgical procedure will occur. Thus, the apparatus of the present invention can be used in a manner (as shown in Fig. 1) such that the second section 32 engages the surface of the heart 2. A slight compressive force is placed on the heart 2 by the

30 apparatus 10 in the area that the surgical procedure will occur so that the heart's movement at that specific area is diminished and stabilized. The stabilizing of the heart

2 is particularly useful for a heart suturing technique in the area of the coronary arteries such as the anastomosis of a bypass graft. In particular, it is advantageous to place a traction suture around an artery 4 using a needle 8 and suture thread 6 while the present invention is stabilizing the surface of the heart 2 adjacent to the artery 4.

5

The elongated handle segment 40 is used to extend the bifurcated member 20 into the chest of the patient to reach the surface of the heart 2. The handle segment 40 has a first end 42 and an opposite second end 44. As shown in Fig. 1, the handle segment 40 preferably has a hand grip 46 disposed on its second end 44.

10

Still referring to Fig. 1, the bifurcated member 20 comprising two elongated prongs 22. Each prong 22 has a proximal end 24 and an opposite distal end 26. Each prong is divided into three sections, a first section 30, a second section 32, and a third section 36. The first section 30 is adjacent the proximal end 24 and terminates in the second section 32. The second section 32 engages the heart 2 and terminates in the third section 36, which is adjacent the distal end 26. It is also preferred that the second sections 32 of each of the two prongs 22 are in the same plane, which is shown in Figs. 1-3.

20

As can be appreciated, the apparatus 10 of the present invention can be used in surgical procedures other than heart surgery, including, for example, soft tissue procedures such as vascular thrombosis repair, intestinal resection and anastomosis and other intra abdominal procedures, and the like.

25

Although including the third section 36 is preferred, a contemplated alternate embodiment does not include this third section 36. However, this embodiment is less desirable. One primary reason is the third section 36 can be used as a tissue retractor or a retractor to pull a selected item, such as surgical thread 6, away from the area that the surgical procedure is being performed. In addition, the third section 36 can be advantageously positioned to secure surgical thread 6 in a cleat 70, which is discussed below.

30

For use in heart surgery, the apparatus 10 has certain size limitations. For example, the available area to a surgeon to perform a minimally invasive surgical procedure on the heart 2 via an intercostal approach is approximately three (3) inches by one and a half ($1\frac{1}{2}$) inches. Accordingly, it is desired that the width between the second sections 32 be in the range of one half ($\frac{1}{2}$) to one and a quarter ($1\frac{1}{4}$) inches, more preferably in the range of three quarters ($\frac{3}{4}$) of an inch to one (1) inch. These widths are narrow enough to fit into the confined space, yet wide enough to bridge the area of interest, e.g., bridge the artery 4 that is to be bypassed, as shown in Fig. 1.

10 In a preferred embodiment, the range for the length of the second section 32 is in the range of one half ($\frac{1}{2}$) inch to one (1) inch, more preferably in the range of two-thirds ($\frac{2}{3}$) of an inch to three quarters ($\frac{3}{4}$) of an inch. In the preferred embodiment, each second section 32 is three quarters ($\frac{3}{4}$) of an inch long and separated by three quarters ($\frac{3}{4}$) of an inch from the other second section 32.

15 The juncture between the first section 30 and the second section 32 forms at least a 90° , or right, angle ϕ therebetween. It is preferred that the angle ϕ be obtuse so that the surgeon has uninhibited access to the area that the surgical procedure is occurring. An acute angle could be used in the present invention, but it is less desirable because it would likely interfere with the surgical procedure.

20 Similarly, it is preferred that the juncture between the second section 32 and the third section 36 also form either a right or an obtuse angle θ therebetween. Although an acute angle is likewise an option, the same problem arises with the interference with the surgical procedure as with angle ϕ . Also, for certain embodiments, it may be desired to use different angles θ in the two prongs. In the preferred embodiment, however, each prong 22 is substantially "U" shape in side view, which can be appreciated from Fig. 1 and also from Figs. 2 and 3, which show a truncated inverted "U" shape.

30 Since the second section 32 engages the heart 2, it is preferable that this section 32 further comprise a means for stabilizing the second section 32 from sliding on the

heart 2. The stabilizing means, in other words, resists sliding or slipping motion between the surface of the heart 2 and the second section 32. Obviously, the stabilizing means should not be of a type that may potentially damage tissue of the heart 2 or other vital organs with which the apparatus 10 is used.

5

In one embodiment shown in Fig. 2, the stabilizing means comprises a textured portion 52 on the second section 32. The surface shown in Fig. 2 is a knurled texture. Other embodiments are contemplated, such as a plurality of intersecting slits therein that prevent the second section 32 from sliding when it engages the heart 2. As can be appreciated, any configuration for the surface of the stabilizing means can be utilized so long as the stabilizing means atraumatically grips the tissue.

Referring to Fig. 3, the stabilizing means can comprise an insert 54 having an attaching surface 56 secured to the second section 32 of each prong 22 and an opposite stabilizing surface 58 which carries the stabilizing means. In Fig. 3, the stabilizing surface 58 of the insert 54 comprises a plurality of tungsten carbide teeth 60. Other materials may be used, however, including stainless steel. As one skilled in the art will appreciate, the teeth should be aggressive enough to prevent sliding, but not so aggressive that they could potentially damage the surface of the heart 2. Now referring to Fig. 4, stabilizing surface 58 of the insert 54 comprises a plurality of flexible hooks 62. The preferred hooks are those of a hook and loop fastener, commonly referred to as VELCRO® fasteners.

Still another embodiment of the stabilizing means is shown in Fig. 5, in which the stabilizing means comprises a plurality of bristles 64. The bristles 64 are disposed at a plurality of different orientations, similar to that of a tube or glass cleaner. Because of the multiple orientations of the bristles 64, any direction that the second section 32 tends to slide is resisted by bristles 64 oriented that direction, which contact the surface of the heart 2 to resist the motion.

30

In another embodiment shown in Fig. 6, the stabilizing means comprises a flexible covering 66 disposed over at least a portion of the second section 32. The covering 66 can be a cloth 68, such as cotton, braided cotton, or linen. Other coverings that resist motion when disposed on the surface of a heart 2 can also be used.

5 another embodiment shown in Fig. 7, the covering 66 is a tubular member 69 selected from the group of silicon, rubber, or plastic. Likewise, other materials that resist motion when disposed on the surface of a heart 2 can also be used.

Another aspect of the present invention is that the apparatus 10 further
10 comprises a means for securing a portion of a surgical thread 6 used in the surgical procedure. In the preferred embodiment, the securing means comprises at least one cleat 70. Referring back to Fig. 1, the cleat 70 is disposed in the distal end 26 of each of the prongs 22 of the bifurcated member 20. Some of the different embodiments for the cleat 70 are shown in Figs 8-11. The preferred embodiment of the cleat 70 that is
15 disposed in the distal end 26 is a slot 72, which is shown in Fig. 8, or a slot with a curved opening 74, which is shown in Fig. 9. Other embodiments to dispose at the distal end 26 include a wedge 76, shown in Fig. 10, or a lateral "V" barrel 78, which is similar in design to a bollard and shown in Fig. 11.

20 Referring again to Fig. 1, it is also preferred to dispose a cleat 70 on either the first end 42 of the handle segment 40 or the proximal end 24 of the bifurcated member 20. More than one cleat 70 can be disposed in this area if the use of the present invention requires multiple cleats 70. As discussed above and shown in Figs. 8-11, the cleat 70 can be selected from the group of a wedge 76, a lateral "V" barrel 78, a
25 protrusion having a slot 72 therein, or a protrusion having a slot with a curved opening 74 therein. As will be appreciated by one skilled in the art, other embodiments of the present invention can use other types of cleats 70 and other locations to dispose the cleats 70.

30 As shown in Fig. 1, the joining means, which joins the handle segment 40 to the proximal ends 24 of the two prongs 22, comprises fixedly attaching the first end 42 of

the handle segment 40 directly to the proximal end 24 of each of the two prongs 22. Alternatively, the joining means can comprise a connecting bar (not shown) disposed so that it is fixedly attached to the first end 42 of the handle segment 40 to form a "T" shape. Each end of the connecting bar is fixedly attached to the proximal end 24 of a respective
5 prong 22.

In another embodiment, the joining means further comprises a means for pivotally connecting the first end 42 of the handle segment 40 to the proximal end 24 of the bifurcated member 20. The advantage of the pivoting means is the second sections
10 32 can be disposed at the predetermined location with the handle segment 40 at a position that facilitates moving the bifurcated member 20. Once properly positioned, then the handle segment 40 can be pivoted to another position and, optionally, locked at that position so that the handle segment 40 does not interfere with the surgical procedure.

15

In the embodiment shown in Fig. 12, the pivotally connecting means comprises a socket 47 disposed on the first end 42 of the handle segment 40 and a ball 48 joined to the proximal ends 24 of the two prongs 22 of the bifurcated member 20. The ball 48 is sized to be complementarily received within the socket 47. Preferably, the joining
20 means further comprises a means for locking the ball 48 in a selective position within the socket 47 so that the handle segment 40 is disposed at a desired pivotal orientation relative to the second sections 32. An example is a tightener 49 that constricts the size of the socket 47 to lock the ball 48 in the desired position. Other pivoting means are contemplated including, for example, a hinged connection (not shown) in which the
25 handle segment 40 only pivots in a plane that is perpendicular to the plane formed by the second segments 36.

Another embodiment that is contemplated of the present invention further comprises a means for attaching the handle segment 40 to a rib spreader 12. Since
30 access to the heart 2 may be achieved using a rib spreader 12, it is desired to have a means to hold the apparatus 10 at the desired stationary position. An attachment 14 to

the rib spreader 12 can serve this purpose. As one skilled in the art will appreciate, there are numerous other options available to attach the handle segment 40 mechanically so that the second section is maintained at a desired position without a person physically holding the apparatus 10.

5

The embodiment shown in Figs. 13 and 14 comprises a coronary stabilizing retractor 10 of the type generally shown in Fig. 1 above but further having prongs 22 (also referred to herein as tines or feet) which have means 23 for allowing adjustment of the distance, spacing or width W1 and W2 between the distal ends 25, 27 of prongs 22.

10 The means 23 for allowing adjustable movement of prongs 22 can be a scissors assembly as shown in Figs. 13 and 14, however other configurations will be apparent to one of skill in the art. In the embodiment shown, handle segment 40 is hollow with an actuator rod 35 slidably disposed within the hollow lumen of handle segment 40. Actuator rod 40 is pivotally connected to scissors hinge (or linkage) assembly 33 at pivot point 37 at
15 the proximal (or free) end of scissors hinge (or linkage) assembly 33. Scissors hinge assembly 33 is pivotally attached to hollow handle segment 40 at its distal (or stationary) end 29.

An adjustment knob 17 is threaded complimentary to threads 19 on the adaptor
20 21 on proximal end of actuator rod 35 such that turning the knob clockwise as shown in Fig. 15A retracts actuator rod 35 proximally and causes movement of prongs 22 to the closed position W2. The surgeon can thus adjust the width of prongs 22 to a desired width over a range of positions between W1 and W2.

25 The embodiment shown in Fig. 16 shows a pair of prongs (tines or feet) 132 which are self-aligning with a surface on which they are placed (such as the heart) having rotation about an axis that is substantially perpendicular to the long axis of scissor extension links (or leg portions) 122. The pair of tines (or feet) 132 can be independently rotatable with respect to each other. The pivotal arrangement shown in
30 Fig. 18 is a preferred means for rotational attachment of prongs (or feet) 132 to scissor extension links (or leg portions) 122.

Figs. 17 shows a preferred means for attachment of actuator rod 135 to scissors hinge (or linkage) assembly 133. Generally the attachment can be a yoke 103 having a slot 105 and complimentary barrel link 107 for threaded attachment to actuator rod 135. Alternatively, yoke 103 can be a single piece attached by a pin 111 to the scissors hinge
5 (or linkage) assembly 133 and having a means such as a threaded engagement (not shown) for attachment to actuator rod 135.

Fig. 19 shows a further embodiment of the invention wherein the prongs (or feet) 132 are configured so as to allow positioning of a rotatable textured sleeve 151
10 over shank portion 153. The textured rotatable sleeves are held in place by cap screws 155.

In a further embodiment, shown in Figs. 20-24, the second section 232 which engages the heart can be fenestrated using slots 274 or holes interspersed between or
15 among a textured gripping surface 276. Prongs 222 of second section 232 have a top surface 270 and a bottom surface 272. Holes or fenestrations 274 extend through the body portion of prongs 222 such that hole 274 communicates the top surface 270 with the bottom surface 272. Alternatively, the fenestrations or slots in the bottom surface 272 do not have to extend all the way through the body of prongs 222 such that a cavity
20 is created in the bottom surface.

It is desirable that the textured surface 276 be adjacent to and surround the fenestrations or holes 274 on the bottom surface 272 of prongs 222. In the embodiment shown in Figs. 23-24, the textured surface 276 is comprised of atraumatic (non-
25 traumatic) teeth 278 for increasing the frictional grip of prongs 222 on the surface of the heart.

When the bottom surface 272 of second section 232 is positioned on the surface of the heart at a predetermined surgical site and gentle pressure is applied, a portion of
30 the heart tissue gently and atraumatically pouches up into or fills the fenestrations or holes 274 to further stabilize the heart and prevent slippage of the stabilizing device at

the predetermined surgical site. The apparatus shown in Figs. 20-24 can be attached via first section 230 to a handle section utilizing, *e.g.*, a ball and socket connection as shown in Fig. 12 and described above.

5

Although the present process has been described with reference to specific details of certain embodiments thereof, it is not intended that such details should be regarded as limitations upon the scope of the invention except as and to the extent that they are included in the accompanying claims.

10

What is claimed is:

1. An apparatus for stabilizing a predetermined area on a heart of a patient to enable a surgical procedure, comprising:
 - 5 a. a bifurcated member comprising two elongated prongs, each prong having a proximal end and an opposite distal end and having a first section, a second section, the first section being adjacent the proximal end and terminating in the second section, the second section which engages the heart;
 - b. an elongated handle segment having a first end and an opposite second
10 end; and
 - c. means for joining the handle segment to the proximal ends of the two prongs of the bifurcated member.
2. The apparatus of Claim 1, wherein the prongs further comprise third section
15 extending from the second section, the third section being adjacent the distal end.
3. The apparatus of Claim 1, wherein the juncture between the first section and the second section forms at least a 90° angle therebetween.
- 20 4. The apparatus of Claim 1, wherein the second section of each prong further comprises means for stabilizing the second section from sliding on the heart.
5. The apparatus of Claim 4, wherein the stabilizing means comprises a textured
portion on at least a portion of one second section.
25
6. The apparatus of Claim 4, wherein the stabilizing means comprises an insert having an attaching surface secured to at least one second section of each prong and an opposite stabilizing surface which carries the stabilizing means.
- 30 7. The apparatus of Claim 6, wherein the stabilizing surface of the insert comprises a plurality of tungsten carbide teeth.

8. The apparatus of Claim 6, wherein the stabilizing surface of the insert comprises a plurality of flexible hooks.
9. The apparatus of Claim 6, wherein the stabilizing surface of the insert comprises a plurality of bristles, the bristles being disposed at a plurality of different orientations from the insert.
10. The apparatus of Claim 4, wherein the stabilizing means comprises a flexible covering disposed over at least a portion of the second section.
11. The apparatus of Claim 10, wherein the covering is a cloth selected from the group of cotton, braided cotton, or linen.
12. The apparatus of Claim 10, wherein the covering is a tubular member selected from the group of silicon, rubber, or plastic.
13. The apparatus of Claim 1, wherein the apparatus further comprises means for securing a portion of a surgical thread used in the surgical procedure.
14. The apparatus of Claim 13, wherein the securing means comprises at least one cleat.
15. The apparatus of Claim 14, wherein one cleat is disposed in the distal end of each of the prongs of the bifurcated member.
16. The apparatus of Claim 15, wherein the cleat is selected from the group of a slot, a slot with a curved opening, a wedge, or a lateral "V" barrel.
17. The apparatus of Claim 14, wherein one cleat is disposed on a selected one of the first end of the handle segment or the proximal end of the bifurcated member.

18. The apparatus of Claim 17, wherein the cleat is selected from the group of a wedge, a lateral "V" barrel, a protrusion having a slot therein, or a protrusion having a slot with a curved opening therein.
- 5 19. The apparatus of Claim 1, further comprising means for attaching the handle segment to a rib spreader.
20. The apparatus of Claim 1, wherein the handle segment further comprises a hand grip disposed on the second end thereof.
- 10 21. The apparatus of Claim 1, wherein the joining means further comprises means for pivotally connecting the first end of the handle segment to the proximal ends of the two prongs of the bifurcated member.
- 15 22. The apparatus of Claim 21, wherein the pivotally connecting means comprises a socket disposed on the first end of the handle segment and a ball joined to the proximal ends of the two prongs of the bifurcated member and sized to be complementarily received within the socket.
- 20 23. The apparatus of Claim 22, wherein the joining means further comprises means for locking the ball in a selective position within the socket so that the handle segment is disposed at a desired pivotal orientation relative to the second sections of the two prongs of the bifurcated member.
- 25 24. The apparatus of Claim 1, wherein the joining means comprises fixedly attaching the first end of the handle segment to the proximal end of each of the two prongs of the bifurcated member.
- 30 25. The apparatus of Claim 4, wherein the juncture between the second section and the third section forms an obtuse angle therebetween.

26. The apparatus of Claim 4, wherein each prong is substantially "U" shape in side view.

27. The apparatus of Claim 1, wherein the second sections of each of the two prongs
5 are in the same plane.

28. The apparatus of Claim 1, further comprising means for causing movement of said bifurcated prongs from a first position to a second position so as to increase or decrease the distance between at least a portion of the prongs.

10

29. The apparatus of Claim 1, further comprising means for allowing rotation of a selected section of the prongs over a predetermined distance about the longitudinal axis of the bifurcated member.

15 30. The apparatus of claim 1, wherein each of the second sections of the two elongated prongs further comprises a body defined by a top surface and a bottom surface and means for enhancing stabilization of the predetermined area.

31. The apparatus of claim 30, wherein the stabilization means comprises
20 fenestrations through at least a portion of the body of the second section forming an opening therethrough such that the top and bottom surfaces are in communication.

32. The apparatus of claim 30, wherein the stabilization means comprises at least one hole through at least a portion of the body of the second section such that the top
25 and bottom surfaces are in communication.

33. The apparatus of claim 30, wherein the stabilization means comprises a textured surface on at least a portion of the bottom surface.

30 34. The apparatus of claim 33, wherein the textured surface further comprises atraumatic gripping teeth.

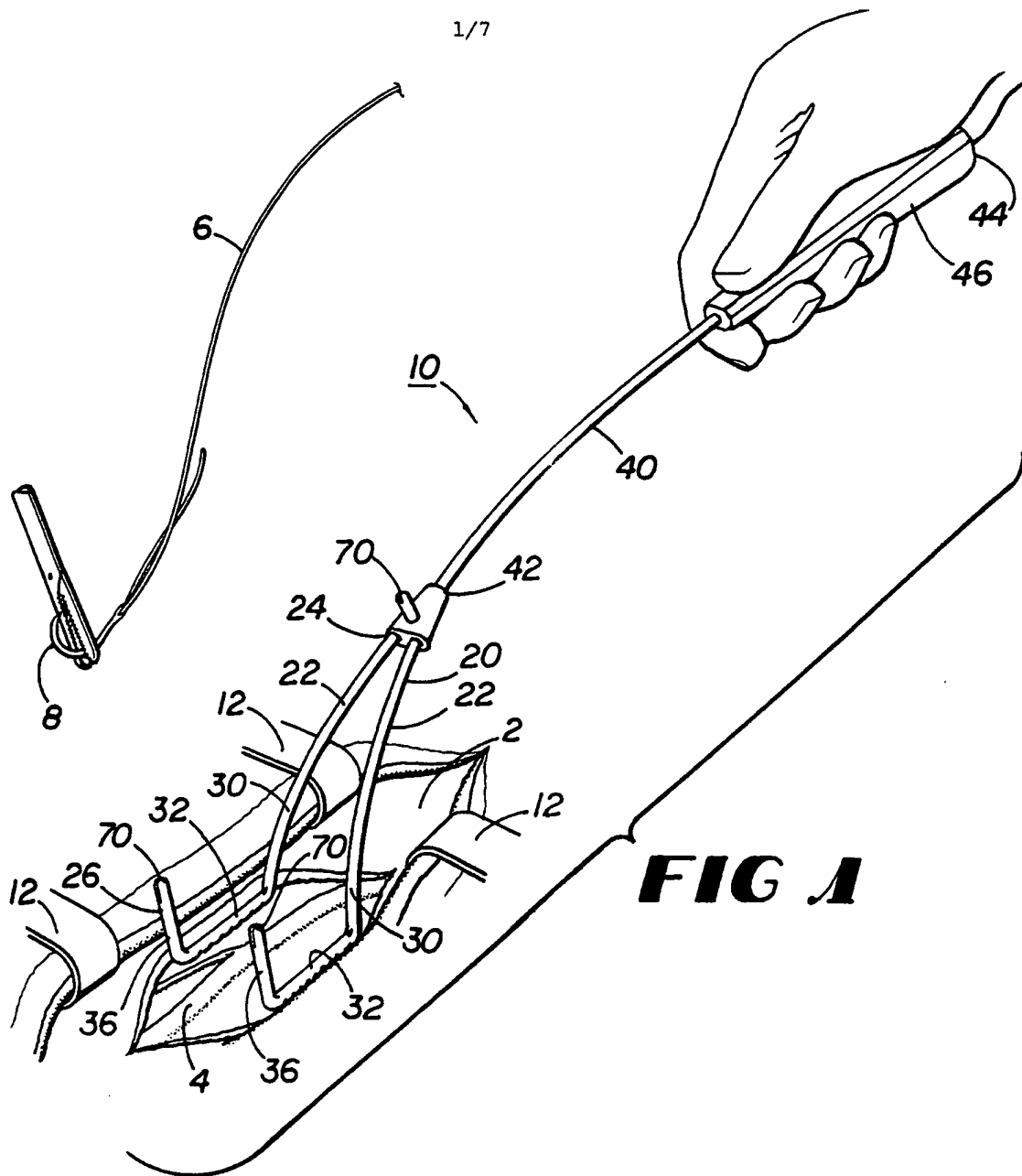


FIG 1

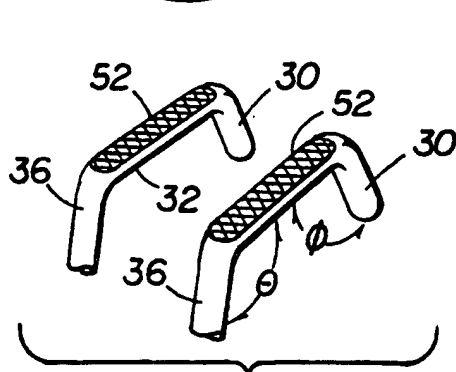


FIG 2

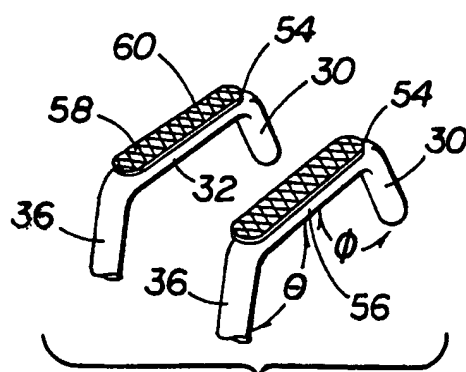


FIG 3

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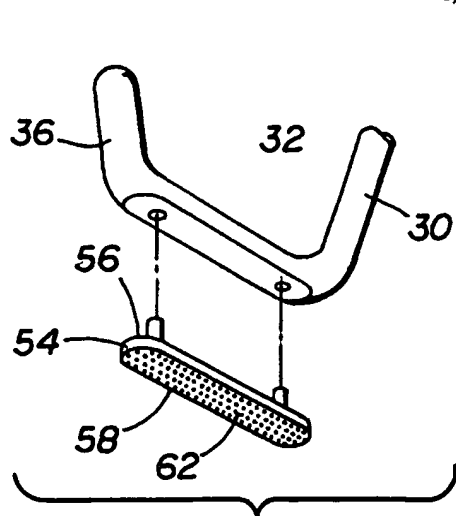


FIG 4

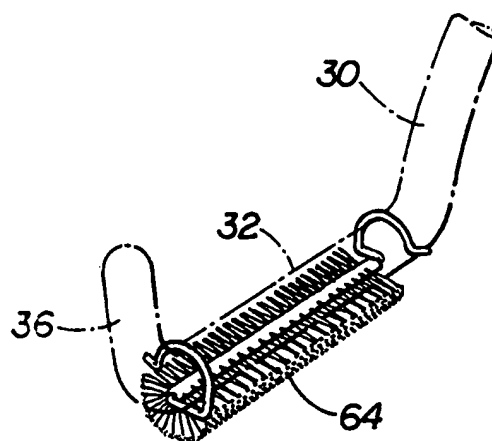


FIG 5

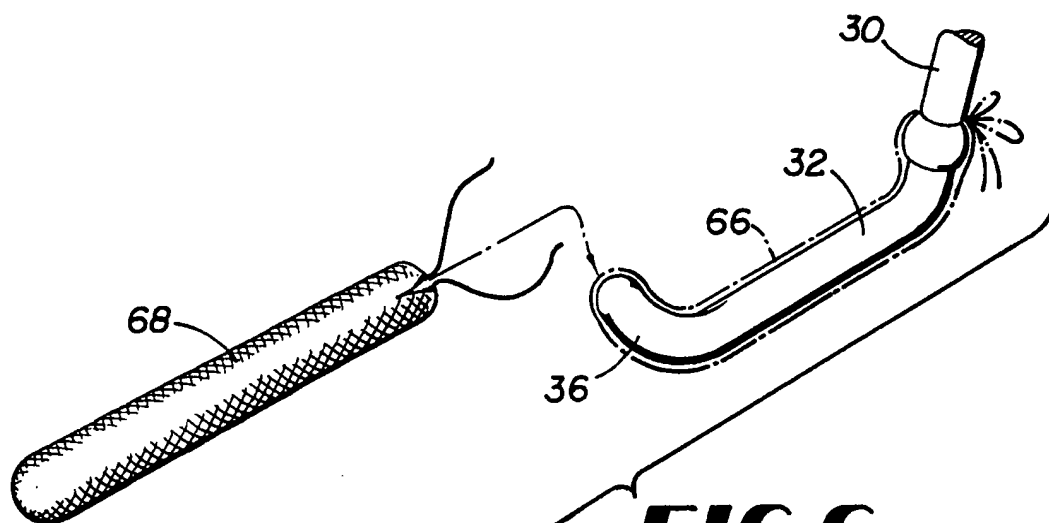


FIG 6

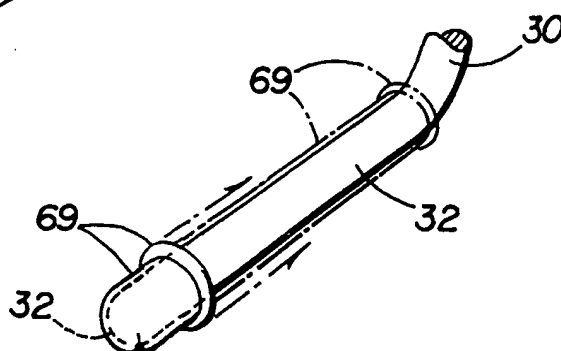


FIG 7

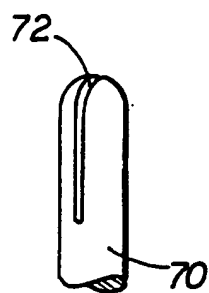


FIG 8

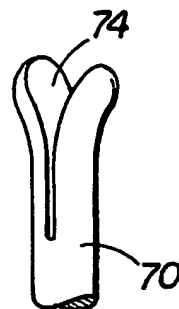


FIG 9

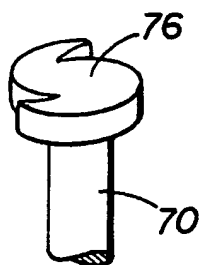


FIG 10

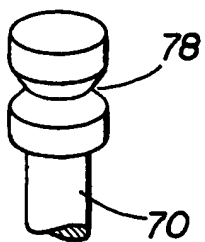


FIG 11

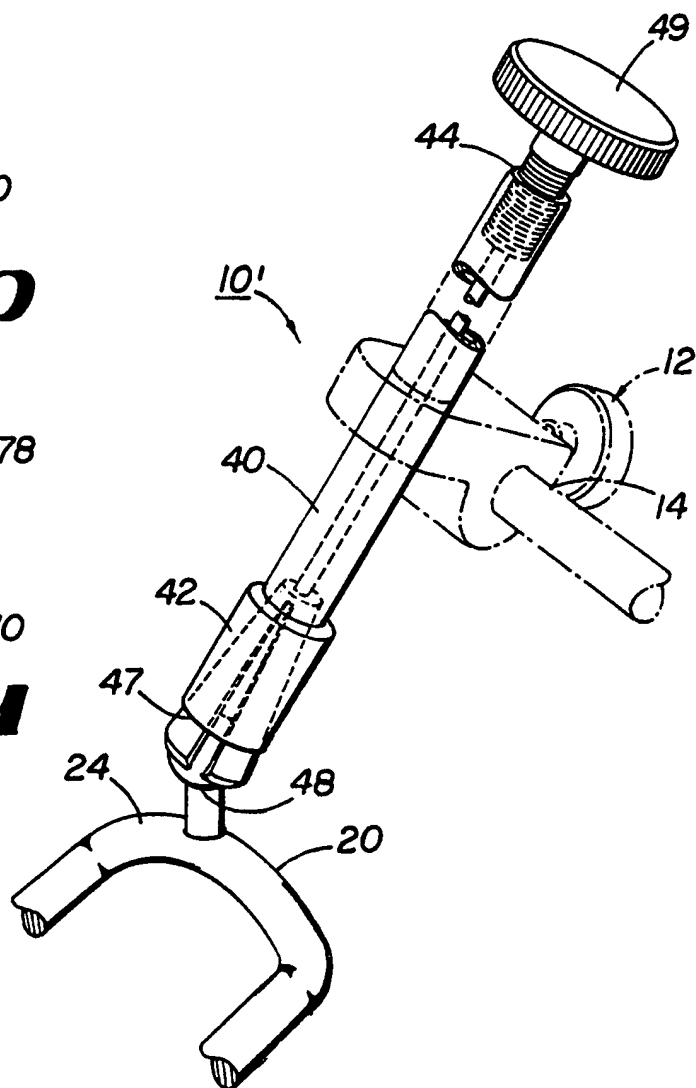
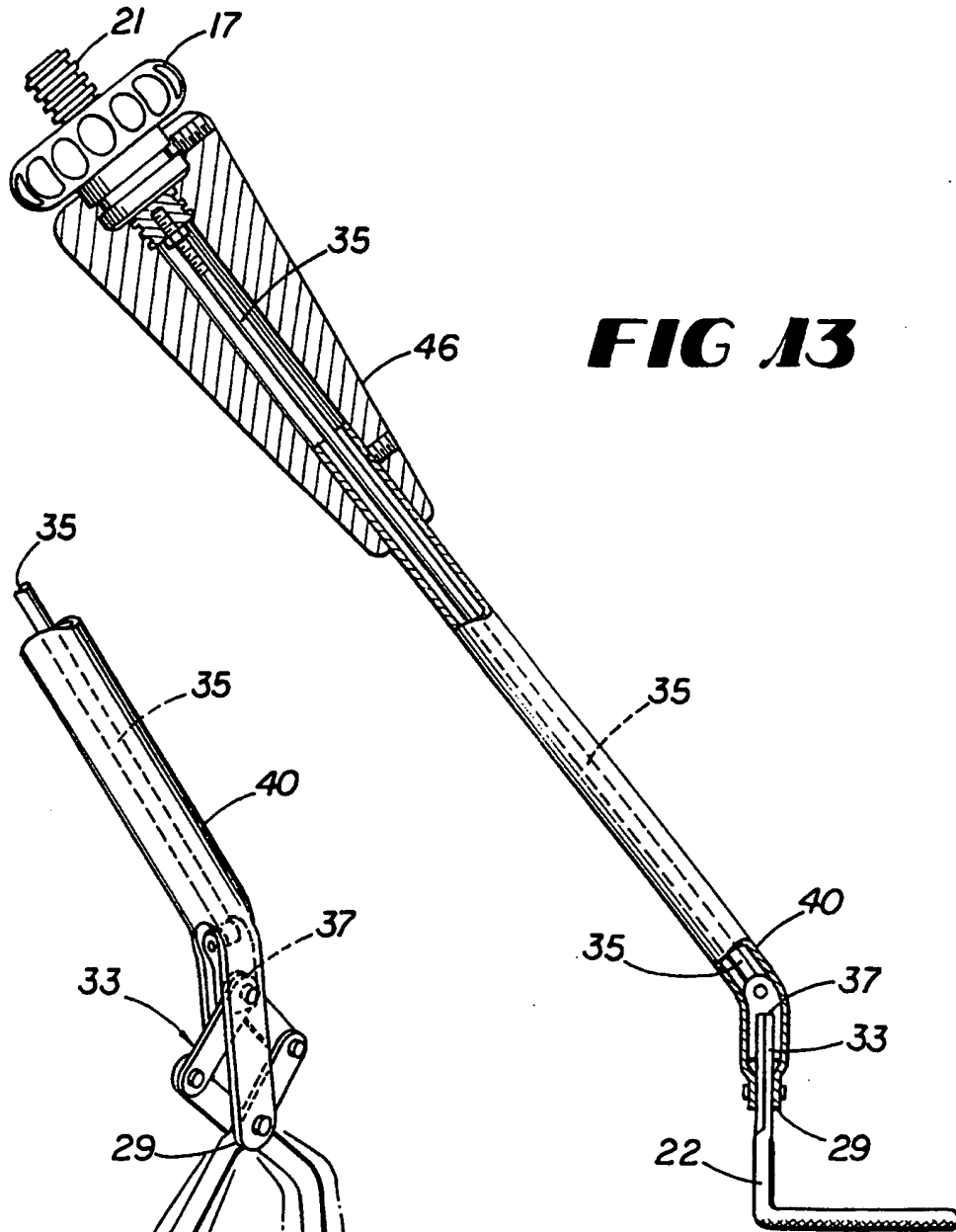
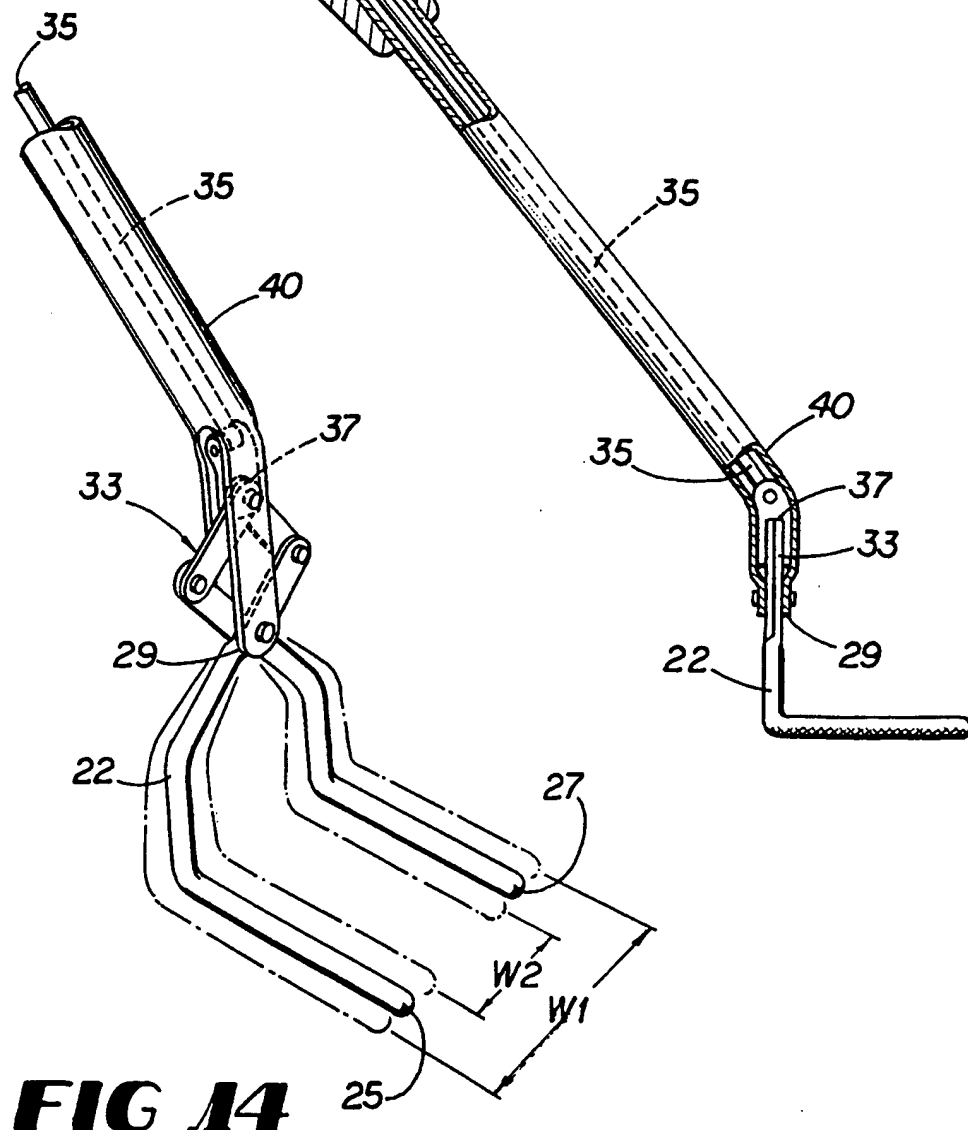


FIG 12

**FIG 13****FIG 14**

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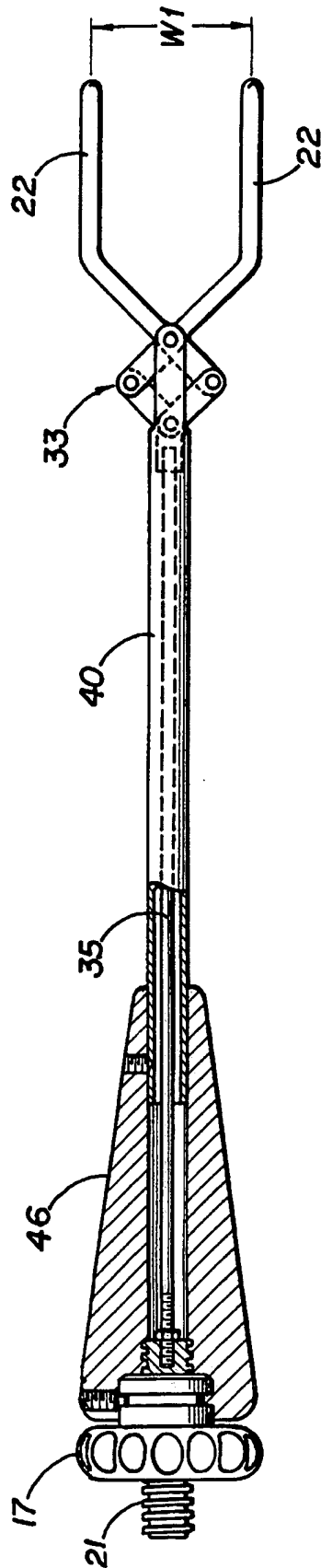


FIG 15

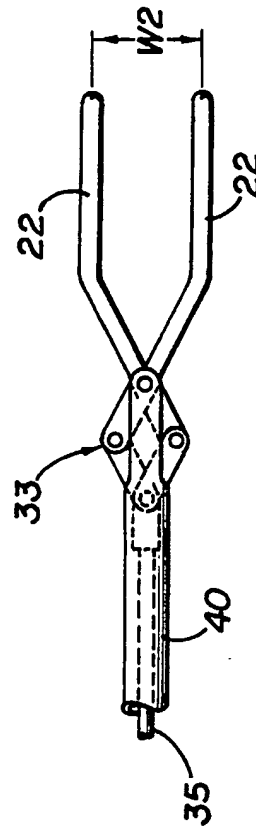


FIG 15A

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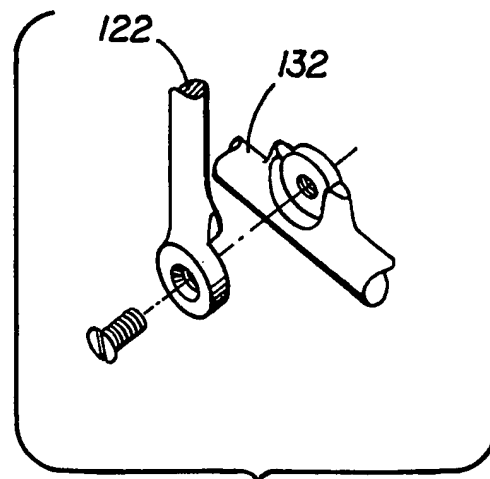
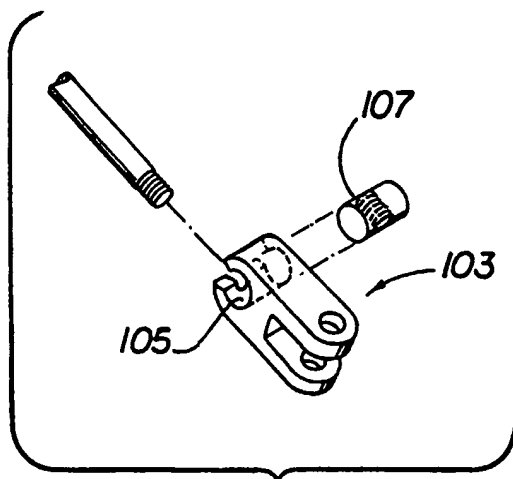
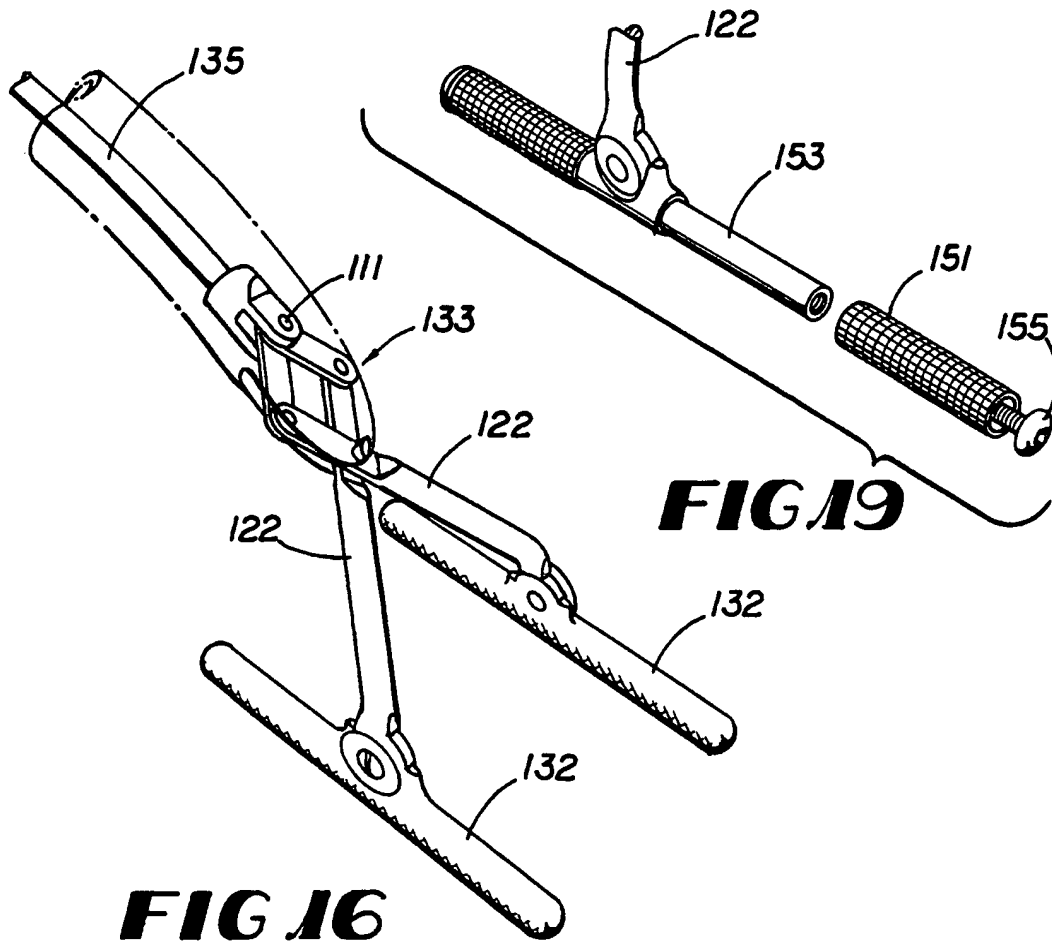


FIG 17

FIG 18

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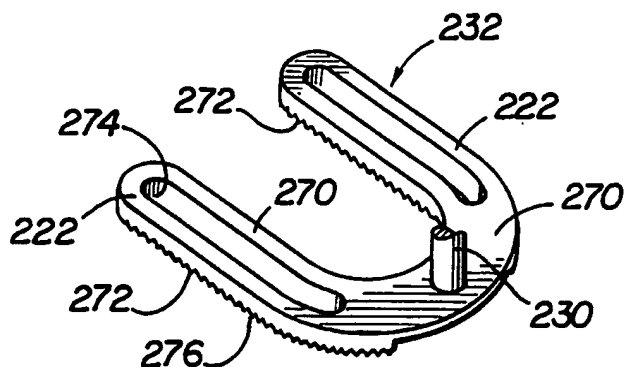


FIG 20

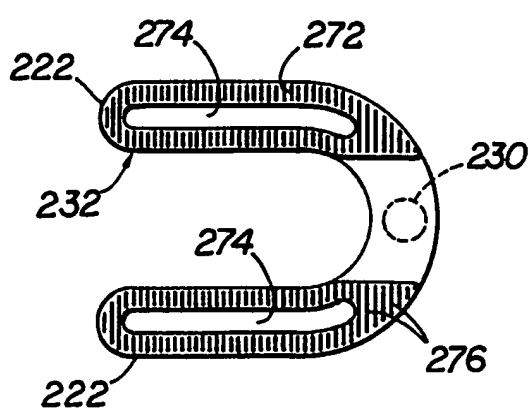


FIG 21

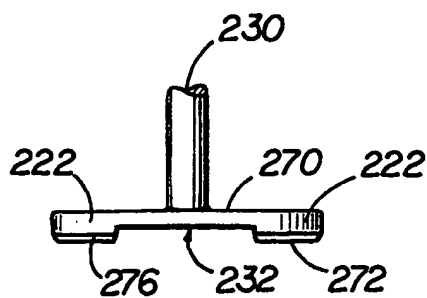


FIG 22

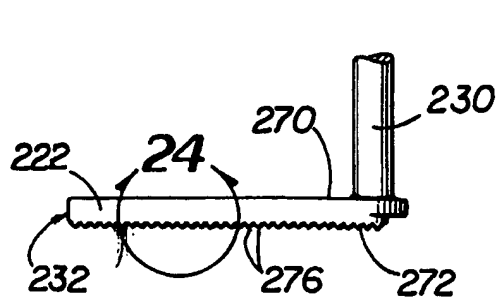


FIG 23

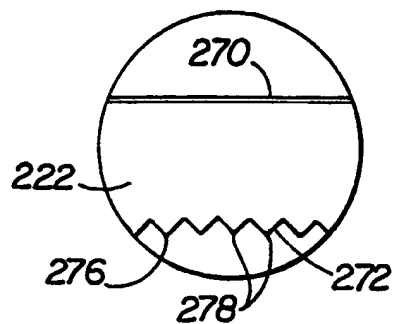


FIG 24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/17411

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/02

US CL : 600/201

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/201-210, 214, 217, 219, 222; 606/001, 107, 119, 205,

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,514,075 A (MOLL et al) 07 May 1996, entire document.	1-3, 13, 20, 21, 27-29
X	US 5,381,788 A (MATULA et al) 17 January 1995, entire document.	1, 2, 4, 5, 13, 20, 21, 27-30, 33, 34

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

12 NOVEMBER 1997

Date of mailing of the international search report

12 DEC 1997

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